

REMARKS

Claims 1-35 and 37-43 will be in the application for further prosecution. Claim 36 has been cancelled. Claims 1-4, 6-11, 18, 20, 21 and 25-30 have been amended to further distinguish the present invention from the cited references, which are discussed below. Please note that Claim 4 was found to have, in error, used single brackets to remove "liquid communication with" in the previous amendment. Assuming that the phrase remains in Claim 4, it has been correctly removed in the above amendments.

Claims 6-20 have been rejected under 35 U.S.C. 112 as indefinite for not positively stating a manipulation step. Claims 6-20 have not been amended to include manipulation steps since these claims include all the limitations of the claims from which they depend and thus only add a description of preferred structures. Thus, these claims include a description of the method of Claim 1 from which they depend. It should be quite clear what method is being covered by the claims. These claims should not be considered indefinite, but merely more limited by including characteristic properties of the microfluidic device. Consequently, reconsideration of the rejection of Claims 6-20 is requested.

Claims 25-28, 29-30, and 36 also have been rejected under 35 U.S.C. 112 as indefinite. Claim 36 was cancelled in the previous amendment, obviating its rejection. Claims 25-28 have been amended to agree with changes to Claims 21, which define the first and second liquids by their volumes. It should now be clear that the volume of the chambers can be determined since they are related to the volume of the liquids to be mixed. Claims 29-30 also have been amended to make it clear that the volume of the first and second chambers can be established with respect to the volume of the liquids to be mixed.

Claims 1-4, 20, 21-22 and 24 have been rejected under 35 U.S.C. 102(e) as anticipated by Koop et al ("Koop") U.S. 6,457,854. The Applicants do not agree that Koop anticipates these claims, since Koop discloses a very different device and method. If Koop anticipated, then if later in time Koop would infringe the present claims, but it could not. Alternatively, all the elements of the present claims must be present in Koop and they are not. Koop contains no first and second chambers, connected through one or more separated capillary passageways. Instead, Koop uses two passageways that intersect many times to mix two liquids.

In order for microfluidic devices to carryout analysis of liquid samples, it is often necessary to mix liquids. However, it is well known that liquids flowing in capillary passageways are in laminar flow, as explained at page 2, line 24 to page 3, line 5. Therefore, the liquids tend to remain separate rather than mix. Consequently, many devices, such as those discussed at page 3, line 12 to page 5, line 7, attempt to overcome the problem, often by improving diffusion between parallel-flowing liquids. In the Applicants' microfluidic devices the chambers are connected by capillary passageways in which flow is expected to be laminar and thus mixing would not be expected. However, the Applicants found that mixing can be achieved when liquids are combined in one chamber and then moved through one or more connecting capillaries to a second chamber. The principles involved are discussed at length at page 13, line 12 to page 18, line 18. Certain factors are believed to result in mixing, as the liquids exit one chamber and exit the capillary(ies) into the second chamber. With regard to the preferred features, such as the space left in the chambers when filled with liquids, or the dimension of the capillaries, or the addition of microstructures to improve mixing, these can be seen to be significantly different from the device described by Koop, which may or may not be properly considered a micro fluidic device.

The Examiner interprets the Koop reference to contain the elements of the Applicant's claimed invention. The Applicants disagree with the Examiner's position.

The Koop device evidently is intended to operate with continuous introduction of two liquids and with the device full of liquids. This can be seen in the following.

- Column 1, line 64 to column 2, line 9

Heat exchange to control temperature throughout the device implies continuous flow; while a device that operates in a batch manner without being completely filled with liquid could not provide temperature control.

- Column 2, lines 38-40 and lines 47-48

Referring to inlet passages supplying two phases implies continuous flow to produce a mixed phase, which is then removed through an outlet passage. The Koop device could not mix two phases if they were not continuously flowing.

- Column 2, lines 59-62

Two phase flows crossing one another and divided a number of times clearly refers to continuous flow of both phases.

- Column 3, lines 26-34

Reference to heat exchangers, pumps, and/or other process engineering components also implies continuous flow, with a completely filled device, or otherwise components could not be effective.

In contrast with the Koop device, it should be evident that the Applicant's device inherently operates in a batch manner without being completely filled. It should be obvious from Figures 1a and 2a that fixed liquid volumes determined by wells 10 and

14 are dispensed from these wells by overcoming stops 12 and 16 and directed into chamber 18 to create a degree of mixing. The mixing process is completed by forcing the combined liquids into a second chamber through one or more capillary passageways. Advantageously, the chambers are larger than the amount of liquids being mixed. That is, the device is not filled. Furthermore, the Applicant's device is particularly useful as an analytical device, which inherently receives a fixed volume of a liquid sample and brings it into contact with a second liquid e.g. a reagent, a diluent, a conditioning agent and the like. Thus, it should be evident that the Applicant's device is, not only physically difference from Koop's, but operates differently. It cannot be seen how the Koop device could be operated in a batch manner, as the Applicants does (note the discussion at "Microfluidics Analytical Devices").

Summarizing the differences between the Koop device and the Applicant's device:

1. Koop's device operates with continuous flow of two phases, while the Applicant's inherently is a batch device operating with liquids disposed from fixed volume wells.
2. Koop has no chambers as defined in the Applicant's specification. They are not larger than the passageways and larger than the volume of liquids.
3. Koop does not have one capillary between two chambers.
4. Koop has two inlets and an outlet, which are not found in the Applicant's device.
5. Koop uses multiple sinusoidal passageways that intersect, while the Applicant's device contains no intersecting sinusoidal passageways.

Claims 3, 6-16, 18-19, 23, 25-35, 38, 40, and 42-43 have been rejected under 35 U.S.C. 103(a) as unpatentable (i.e. obvious) over Koop. Each of these claims depends from independent Claims 1 or 21 and should be allowable if the independent claims are allowed. The Applicants contend that Claims 1 and 21 are not anticipated by Koop, but also that they should not be obvious. If Koop teaches forcing two liquids into intersecting sinusoidal passages, it does not follow that one skilled in the art would substitute two chambers connected by one or more separated capillary passageways, since laminar flow would be expected.

The subject matter claimed in dependent claims 3, 6-16, 18-19, 23, 25-35, 38, 40, and 42-43 does not involve optimum values reached by routine skill in the art. Making such an extrapolation from Koop, who teaches a very different mixing device cannot be considered feasible. While it would be reasonable to make such an argument in some instances, it is not persuasive here, where the two devices are so different.

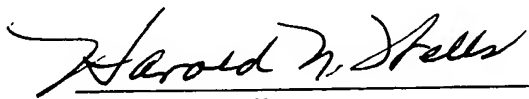
Claims 5, 17, 37, 39, and 41 have been rejected under 35 U.S.C. 103(a) as unpatentable over Koop in view of Jakajima et al [sic] (Nakajima). The deficiencies of Koop have already been discussed. Nakajima described an improved device to create microspheres, which involved structures that are far different from those of the Applicants' device. The Examiner relies on "obvious to one skilled in the art" to combine Nakajima with Koop. However, there is no suggestion anywhere that combining Nakajima with Koop would yield the Applicants' invention.

Many additional references were cited, but not applied against the present claims. None of these are believed to be more pertinent than those used by the Examiner. Many of these patents involve movement or separation of liquids by electromotive means, rather than mixing of liquids. Hillman et al discusses microfluidic devices in which liquids are moved by capillary action and mentions the use of sonication for mixing and vanes to create turbulence.

The Examiner is asked to enter the proposed amendments, reconsider his rejection, and allow the amended claims. If further amendment is believed necessary, the Examiner is invited to contact the Applicants' attorney, at the telephone number provided below.

Respectfully submitted,

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Date



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